

### **REMARKS**

Claims 1-17 and 23-27 are pending in the application and are at issue.

This response is submitted in accordance with 37 C.F.R. §1.116(a) and §1.116(b) in order to present the rejected claims in a better form for allowance or appeal. The response is necessary to eliminate rejections under 35 U.S.C. §103. This response was not presented earlier because applicants' believed, and still believe, that the response of May 10, 2010 overcame all outstanding rejections. This response should be entered because it places the application in better form for allowance or appeal, and the response does not require further searching or present any new issues.

Claims 1, 3-15, 23-25, and 27 stand rejected as being obvious under 35 U.S.C. §103 over Wada et al. U.S. Patent No. 5,797,893 ('893) in view of Abuelyaman et al. U.S. Patent Publication No. 2001/0020062 ('062 publication), Tomalia et al. U.S. Patent No. 4,507,466 ('466), and Wada et al. U.S. Patent Publication No. 2004/0048955 ('955 publication).

The basis of this rejection is that the '893 patent discloses an absorbing agent composition containing absorbent organic polymer particles, a water-insoluble inorganic powder, and a polyamine compound, and the '062 publication discloses a dendritic polymer dispersant for inorganic hydrophobic particles. The examiner contends that it therefore would have been obvious to utilize a dendritic polymer of the '062 publication in the absorbing composition of the '893 patent. The '466 patent is cited for disclosing specific dendritic polyamidoamines. The '955 publication adds little or nothing to the '893 patent. Applicants traverse this rejection.

Claim 1 recites swellable hydrogel-forming polymer particles having at least one hydrophilic polymer of dendritic structure (dendritic polymer) and at least one water-insoluble phosphate present on the surfaces of the particles.

As previously noted, Example 5 provides an excellent description of the invention recited in independent claim 1 and the dependent claims. This description is

provided in the response of May 10, 2010, at pages 5 and 6, and is not repeated here for the sake of brevity, but is incorporated by reference.

The proper bases to support an obviousness rejection under 35 U.S.C. §103 also were presented in the response of May 10, 2010, and are not repeated here for the sake of brevity.

However, applicants note that the Court in *KSR Intern. Co. v. Teleflex Inc.*, 127 S.Ct., 1727, 1742 (U.S. 2007) held that a patent composed of several elements is not proved obvious merely by demonstrating that each of the elements was, *independently*, known in the prior art (*KSR*, 127 S.Ct. at 1741). The mere fact that the prior art may be modified in the manner suggested by the examiner does *not* make the modification obvious unless the prior art suggests the desirability of the modification. *In re Gordan*, 733, F.2d at 902, 221 USPQ at 1127. *In re Fritch*, 23 USPQ 2<sup>nd</sup> 1780, 1783-1784 (Fed. Cir. 1992). Applicants also respectfully note that MPEP §§2142 and 2143 require that the teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicants' disclosure. *In re Vaeck*, 947 F.2d 4899 (Fed. Cir. 1991). The examiner may be utilizing the teachings of the specification in an attempt to modify the references to allegedly arrive at the claimed invention. It is impermissible to use the claimed invention as an instruction manual or "template" to piece together the teachings of the prior art so that the claimed invention is rendered obvious. *In re Gorman*, 933 Fed. 2<sup>nd</sup> 982, 987, 18 USPQ 2<sup>nd</sup> 1885, 1888 (Fed. Cir. 1991). *In re Fritch*, 23 USPQ 2<sup>nd</sup> 1780 at 1784 (Fed. Cir. 1992).

The '893 patent discloses an absorbing agent composition containing an absorbent resin, a water-insoluble inorganic powder, and a polyamine compound (column 5, lines 17-38). Numerous polyamine compounds are disclosed in the '893 patent at column 10, line 57 through column 11, line 59. The examiner *correctly* states that the '893 patent *fails* to teach or suggest *any* dendritic polymer, and the extensive list of polyamines disclosed in the '893 patent contains *no* dendritic polymers. It is important to note that the '893 patent states that the polyamine "*must contain*" at least one of a primary, secondary, or tertiary amino group, i.e., a nitrogen containing group ('893 patent, column 10, lines 53-57). It also must be

noted that an amino group of an amine, i.e.,  $-NR_2$ , is different in structure, reactivity, and properties from an amido group of an amide, i.e.,  $-C(=O)NR_2$ .

The examiner referred to the "polyalkyleneimine" and "polyamidopolyamine" in the list of polyamine examples of the '893 patent. However, as explained in a prior response, such polyamines have a structure substantially different from a *dendritic* polymer. Applicants previously provided Exhibits A-H showing the structure of a dendritic polymer and how this structure differs from the standard polyamines disclosed in the '893 patent. In short, the term "polyamine" or "polyamidoamine" defines the functional groups and types of bonding in the polymers, but *not* the *structure* of the polymer. See pages 7-10 of applicants' prior response of September 28, 2009. It is well known in the art that different polymer structures lead to different properties.

The '893 patent provides no teaching or suggestion that would have led a person skilled in the art to substitute a dendritic polymer for a polyamine of the '893 patent. The '062 publication fails to cure the deficiencies of the '893 patent.

The '062 publication discloses dispersants that adsorb to *hydrophobic* inorganic particle surfaces (abstract) and prevent the agglomeration of *hydrophobic* particles (paragraph [0027]). The hydrophobic particles disclosed in the '062 publication are inorganic compounds, such as insoluble pigments (paragraphs [0059]-[0063]). The dispersant reduces the tendency of *hydrophobic* particles to agglomerate. The '062 publication discloses a "hydrophobic particle" that is nonpolar or has a nonpolar surface ('062 publication, paragraph [0027]). The '062 publication is not remotely directed to the *claimed hydrogel* forming polymer particles, which are polar, are *hydrophilic*, and have polar surfaces. The inorganic compounds of the '062 publication are substantially different from organic water-absorbing particles, in structure and in properties.

Applicants fail to see a common sense incentive from the '062 publication for a person skilled in the art to utilize a dendritic polymer in connection with a hydrophilic polymer of the '893 patent. The '062 publication is limited to preventing agglomeration of hydrophobic inorganic particles and provides no reasonable expectation of success when used with hydrophilic polymer particles. In addition, the '062 publication, directed to dendritic

polymers that prevent agglomeration, contains no teaching or suggestion of any effect on the absorbing properties of a polymer. In fact, there could not be any such teaching because the '062 publication is *limited* to hydrophobic particles, i.e., particles that repel rather than attract water.

Applicants show in the specification that a combination of dendritic polymer and water-insoluble phosphate or a water-absorbing particle surface drastically increase the SFC value of the particles from 33-35 to 62. Applicants specifically point to Table 1, at page 22 of the specification, wherein the *combination* of a claimed dendritic polymer and claimed water-insoluble phosphate (Example 4) provided unexpected and unpredicted improvement in SFC values over Examples 1-3, which included neither or only one of the dendritic polymer and water-insoluble phosphate. Also see Examples 5 and 6. The dendritic polymer used in the present examples is BOLTORN<sup>®</sup> 40. See previously provided Exhibit B, i.e., WO 2008/071575, pages 4 and 5, for the structures of a dendritic polymer recited in claims 2, 3, 26, and 27. Such dendritic polymers are not disclosed in the '062 publication. Such a result could not have been predicted from a combination of the '893 patent and the '062 publication.

To illustrate the importance of the SFC value, applicants submit concurrently with this response the relevant portions of Goldman et al. U.S. Patent No. 5,599,335 ('335) as Exhibit A. Exhibit A explains that SFC values demonstrate the permeability of a hydrogel layer formed from hydrogel-forming polymers. The present invention greatly improved this important absorption property of a hydrogel-forming polymer, which could not have been predicted from the cited references, i.e., the '893 patent is silent with respect to dendritic polymers and SFC has *no meaning* for a hydrophobic inorganic particle that does not absorb water.

Further, the dispersants of the '062 publication are dendritic polymers that have been *modified* by chemical reactions "to attach ionizable moieties and peripheral nonpolymerized nonpolar hydrocarbon hydrophobic moieties" ('062 publication, paragraph [0047]). See [0081]-[0084] of the '062 publication, wherein the BOLTORN dendritic polymers (the type used in the present examples, and claimed in claims 2 and 26 are highly modified to provide the dispersants of the '062 publication. Importantly, the BOLTORN H30 that is modified in the '062 publication (see paragraphs [0082]-[0083]) is *not* a polyamine, but

rather is a polyhydroxy compound free of amino groups (see structure of BOLTORN H30 in Exhibit C previously provided with Amendment "B" on September 28, 2008). The examiner is reminded that the '893 patent *requires* a polymer bearing amino groups.

The dispersants of the '062 publication therefore have a structure substantially different from the dendritic polymer used as a starting material, and neither the modified nor the unmodified dendritic polymer of the '062 publication are polyamines. The '893 patent *requires* a polyamine, and accordingly a person skilled in the art would not substitute a *modified* or an *unmodified* dendritic polymer disclosed in the '062 publication for a polyamine of the '893 publication. Further, the '062 publication fails to teach or suggest using a dendritic polymer that has *not* been modified as a dispersant.

In view of the teachings of the '893 patent and '062 publication, a person skilled in the art would not have combined the references in a way that leads to the presently claimed invention. As stated above, a substitution of the polyhydroxy dendritic polymer (modified or unmodified) disclosed in the '062 publication destroys the teachings of the '893 patent which explicitly discloses the *need* for a polyamine. It is submitted that a person skilled in the art would have had no incentive or apparent reason to make this substitution, let alone a substitution using an unmodified dendritic polymer.

Not only does the '062 publication disclose dendritic polymers that do not contain the amino groups that are explicitly taught as necessary by the '893 patent, the '062 publication utilizes a *modified* dendritic polymer to prevent agglomeration of *hydrophobic* particles. The '062 publication defines hydrophobic particles as being non-polar. However, the claimed hydrogel forming particles are *hydrophilic*, i.e., water absorbing. A person skilled in the art therefore would have had no apparent reason to position a modified dendritic polymer of the '062 publication, or any unmodified dendritic polymer, on a *hydrophilic*, hydrogel-forming particle.

If the examiner contends that a modified dendritic polymer of the '062 publication would be positioned on a hydrogel-forming particle because of the presence of a water-insoluble phosphate, such a substitution would not be made for the reasons set forth above. The '062 publication specifically teaches that a dendritic polymer *must be* modified to

perform as a dispersant for a hydrophobic particle. The '062 publication fails to teach or suggest that an unmodified dendritic polymer can perform as a dispersant and the '893 patent requires a polyamine, thus substitution of an unmodified dendritic polymer on a hydrogel-forming particle coated with a water-insoluble phosphate would not provide a predictable result.

Further, it is submitted that in view of the substantial difference in structure between a polyamine disclosed in the '893 patent and a modified or unmodified dendritic polymer, a person skilled in the art would not have substituted a dendritic polymer for the polyamine of the '893 patent with any reasonable or predictable expectation of providing a hydrogel forming particle having improved properties, as disclosed in the '893 patent.

Importantly, a person skilled in the art could not have predicted the unexpected jump in SFC values provided by the presently claimed invention, as demonstrated in Table 1 of the specification, from a combination of the '893 patent in combination with the '062 publication.

It is submitted therefore that a combination of the '893 patent and the '062 publication does not render the present claims obvious. The '466 patent and '955 publication do not cure the deficiencies of the '893 patent and '062 publication. The '955 publication adds nothing to the '893 patent; both are directed to water-absorbing particles. See '893 patent, columns 5-9. The '466 patent merely discloses various *unmodified* dendritic polymers with no suggestion as to their use with hydrogel-forming polymer particles. The dendritic polymers of the '446 patent can be *starting* materials for the modified dendritic polymer of the '062 publication.

Therefore, it is submitted that a combination of the '893 patent, '062 publication, '466 patent, and '955 publication fails to render the present claims obvious.

At pages 3-5 of the Office Action, the examiner provides responses to applicants' previous arguments. However, the examiner neglects applicants' reasoning that a person skilled in the art would have had no incentive to use a dendritic polymer as a replacement for the polyamide-polyamine or the '893 patent because:

(a) the dendritic polymer of the '062 publication is used to prevent agglomeration of hydrophobic inorganic particles; and

(b) the '893 patent is directed to hydrophilic, organic particles. Where is the incentive *from the cited art* to make the substitution suggested by the examiner?

Further, how could it have been predicted that a dendritic polymer in combination with a water-insoluble phosphate would increase the SFC value for a hydrogel-forming polymer coated only with a water-insoluble phosphate *or* a dendritic polymer from the mid-30's to the mid-60's for a hydrogel-forming polymer coated with both the water-insoluble phosphate and the dendritic polymer. It is established that for an examiner to rely upon a "substitution" rationale to support a rejection, the results of the substitution must be predictable.

At paragraphs 11-12 of the Office Action, the examiner states:

"11. In response, it is noted that paragraphs [0053] and [0083] of Abuelyaman et al exemplify dendrimers based on *polyester*, and, therefore, the remaining nucleophilic functional groups are based on polyol. However, this should not be misconstrued as a teaching that the dendrimer of Abuelyaman et al can have *only* hydroxyl groups.

12. Paragraph [0044] teaches that in addition to **polyester, the dendritic polymer can be a polyamide**, which is commonly known within the art to be the reaction product of polycarboxylic acid and polyamine. One of ordinary skill would understand that when using polyamide instead of polyester, the replacement of polyol for polyamine as the nucleophilic species would result in an amine-functional dendrimer. Thus applicants' position that Abuelyaman et al fail to teach amine-functional dendrimers is not persuasive."

The examiner's reasoning is incorrect. Paragraph [0044] of the '062 publication teaches that the dendritic structure can be any of polyamide, polyester, polyether, etc. However, this is for the *internal* structure of the dendritic polymer. As stated in paragraph [0044], such compounds are "reacted with another compound to provide the *ionic* peripheral groups suitable for use in the invention. Accordingly, the '062 publication does

*not* teach amine-functional dendritic polymers, but teaches modified dendritic polymers as explained above.

At page 4, paragraph 13, of the Office Action, the examiner states:

"13. Still if applicants maintain that it would not be obvious to *replace* the dendrimers of claims 3 and 27 into Wada et al ('893), the examiner would like to point out that claim 1 merely requires hydrophilic dendrimers (regardless of whether they are modified or unmodified). Therefore, claim 1 is still rendered obvious since, at the least, it would be obvious to combine the composition of Wada et al ('893) with the dendrimers of Abuelyaman et al based on the motivation that the dendritic polymers are useful with water-insoluble compounds — which Wada et al ('893) requires."

First, the dendritic polymer of the '062 publication are useful with *hydrophobic* inorganic particles. The '893 patent is directed to *hydrophilic* organic particles. The examiner has provided no *factual* reasoning to support this suggested substitution, but merely unsupported conjecture. Further, the present claims provide unexpected results that could *not* have been *predicted* from any arguable combination of the '893 patent and the '062 publication.

In addition, the examiner is giving the claims an unreasonably broad interpretation by including unmodified and modified dendrimers within the scope of claim 1. The '062 publication is clearly directed to modified dendrimers throughout the specification and claims. The present specification fails to teach or suggest a modified dendrimer and would not support a claim directed to a modified dendritic polymer.

Applicants note that the claims are given the broadest *reasonable* interpretation during examination. However, an examiner cannot give the claims an incorrect interpretation. As stated in *In re Skvorecz* (580 F.3d 1262, 1267 (Fed. Cir. 2009)):

"The protocol of giving claims their broadest reasonable interpretation during examination does not include giving claims a legally incorrect interpretation. This protocol is solely an examination expedient, not a rule of claim construction. Its purpose is to facilitate exploring the metes and bounds to which



the applicant may be entitled, and thus to aid in sharpening and clarifying the claims during the application stage, when claims are readily changed. See *In re Buszard*, 504 F.3d 1364, 1366 (Fed. Cir. 2007); *In re Cortright*, 165 F.3d 1353, 1358 (Fed. Cir. 1999).

Also see *In Re Ravi Vaidyanathan* (CAFC 2009-1404, May 19, 2010) stating:

"The PTO Solicitor responds that the broadest reasonable claim interpretation that is supported by the specification is adopted during examination, for the claims can readily be amended during examination, to impart precision if needed. We agree with this protocol as an examination expedient, for its purpose is to aid in sharpening the claims in order to avoid ambiguity or uncertainty in the issued patent. See e.g., *In re Skvorecz*, 580 F.3d 1262, 1267 (Fed. Cir. 2009); *In re Buszard*, 504 F.3d 1364, 1366–67 (Fed. Cir. 2007); *In re Prater*, 415 F.2d 1393, 1396 (CCPA 1969). However, the PTO's "broadest" interpretation must be reasonable, and must be in conformity with the invention as described in the specification.

The Board's interpretation of claim 9 finds no support in the '203 specification, and is not a reasonable interpretation under the rules of claim construction. The description in the specification consistently indicates that the neural network guides the munition all the way intercept. The '203 specification uses the word "strike" synonymously with "intercept," foreclosing the divergent meanings the Board seeks to attach to these terms. The Board's rejection of claims 8 and 9 was based on an incorrect interpretation of these claims. That rejection is vacated and remanded for reconsideration under the correct interpretation of the claims, and in further view of the issues with respect to obviousness as discussed in connection with claims 1–7." (Emphasis added)

It should further be noted that claims 2, 3, 26, and 27 are directed to *unmodified* dendritic polymers.

The examiner's comment that it would have been obvious to substitute the polyamine of the '893 patent with a dendritic polymer of the '062 publication is mere speculation unsupported by the references, but rather destroyed by the '893 patent. The '893 patent explicitly requires a polyamine. The '062 publication does not disclose a polyamine, but rather a dendritic polyol (see '062 publication paragraphs [0081]–[0084]). Further, the

'062 publication seeks to avoid agglomeration of *hydrophobic inorganic* particles. Hydrogel-forming particles are organic and hydrophilic. Accordingly, the combination of references provides no apparent reason for a person skilled in the art to modify the references in the way presently claimed. The examiner has failed to provide any factual reasoning that would support the proposed modification.

This is the type of rejection also addressed by the CAFC *In re Vaidyanathan*, May 19, 2010 (2009-1404), wherein in reversing an obviousness rejection sustained by the Board, the court stated the following:

"Obviousness is determined as a matter of foresight, not hindsight. *See id.* at 421 (citing *Graham*, 383 U.S. at 36). *KSR* did not free the PTO's examination process from explaining its reasoning. In making an obviousness rejection, the examiner should not rely on conclusory statements that a particular feature of the invention would have been obvious or was well known. Instead, the examiner should elaborate, discussing the evidence or reasoning that leads the examiner to such a conclusion. Generally, the examiner cites prior art references to demonstrate the state of knowledge. *See* 37 C.F.R. §1.104(c)(2)... In these cases the examiner should at least explain the logic or common sense that leads the examiner to believe the claim would have been obvious. Anything less than this results in a record that is insulated from meaningful appellate review. *Zurko*, 258 F.3d at 1386. If the examiner is able to render a claim obvious simply by saying it is so, neither the Board nor this court is capable of reviewing that determination. *See KSR*, 550 U.S. at 418, citing *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006) ("[R]jections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.").

Because there is insufficient elaboration of the examiner's or the Board's reasoning in this record, we vacate the Board's rejection of claims 1–7. We remand for redetermination of the question of obviousness. On remand, the PTO should determine obviousness based on evidence of record or on the examiner's detailed and articulated reasoning. If there is neither record evidence nor detailed examiner reasoning, the Board should not conclude that Vaidyanathan's claims are obvious."

Claims 2, 3, 26, and 27 recite *unmodified* dendritic polymers. The '893 publication is silent with respect to dendritic polymers. The '062 publication requires a modified dendritic polymer. The '466 patent discloses various dendritic polymers, without *any* disclosure relating to applying a dendritic to a particle. Jumps in logic that require substituting an unmodified dendritic polymer of the '466 patent for the modified dendritic polymer of the '062 publication (to which the '062 publication is limited), then further substituting the unmodified dendritic polymer for the polyamidoamine of the '893 (which fails to teach or suggest a dendritic polymer) patent can only be justified from a hindsight reconstruction of the claims. Neither substitution is taught or suggested by the combination of cited references, and are contrary to the explicit teachings of the references in combination.

With respect to comments made by the examiner in a prior Office Action, a statement that the '062 publication is directed to *polymer* systems is incorrect. The '062 publication is directed to pigment systems, i.e., '062 publication discloses a hydrophobic pigment particle having a hydrophobic polymer and a modified dendritic polymer on the surface particle surface (see '062 publication, Fig. 2). The present claims recite a hydrogel-forming particle (hydrophilic) having a phosphate and an unmodified dendritic polymer on the particle surface.

The examiner stated that the '466 patent teaches the same polyamines as the '893 patent. This is incorrect and inconsistent with the examiner's statement in the Office Action that the '893 patent fails to teach a dendritic polymer. The '893 patent merely discloses polyamines that are not dendritic; the '466 patent is limited to dendritic polymers.

In view of the above comments, the examiner is reminded of the recent decision of *In re Chapman* (CAFC 2009-1270), wherein the court stated that misunderstanding a reference is not harmless error because it increases the likelihood that an applicant is erroneously denied a patent on grounds of obviousness. In such a situation, an examiner's conclusion regarding obviousness are called into question.

With respect to claim 7, the examiner previously relied upon a result-effective variable theory to support the rejection. This is an improper basis to reject claim 7. For an

examiner to rely upon a result-effective variable, the variable must be recognized *in the art* as result effective for the variable claimed. The cited art is totally silent with respect to hollow microspheres, let alone hollow microsphere of a specific wall thickness and diameter. Accordingly the inclusion of hollow microspheres cannot be termed result effective. See MPEP §2144.05II.B. In addition, because *multiple* variables control absorbent phase density and strength, and diaper weight, the result-effective variable rationale used of the examiner does not apply. Further, because the cited art *fails* to teach or suggest hollow microspheres, claim 7 cannot be rejected as being obvious simply because the art fails to teach or suggest every element recited in the claim. Finally, the examiner's rationale that the hollow microspheres would lead to a lighter diaper is pure conjecture and unsupported by the art.

In the present Office Action at paragraph 14, page 4, the examiner now supports the rejection of claim 7 stating that the diameter and wall thickness of the hollow microspheres are basic parameters and no unexpected results are demonstrated. However, because the cited art fails to *even* teach or suggest hollow microspheres, no unexpected results are required.

For all the reasons set forth above, it is submitted that claims 1, 3-15, 23-25, and 27 would not have been obvious under 35 U.S.C. §103 over a combination of the '893 patent, '062 publication, '466 patent, and '895 publication, and that the rejection should be withdrawn.

Claims 2 and 26 stand rejected under 35 U.S.C. §103 as being obvious over the '893 patent in view of the '062 publication, the '466 patent, the '955 publication, and Holt et al. U.S. Patent No. 5,418,301 ('301). Applicants traverse this rejection.

The patentability of the claims over a combination of the '893 patent, '062 publication, '466 patent, and '955 publication has been discussed above. The '301 patent does not overcome the deficiencies of these four cited references. The '301 patent is relied upon for a disclosure of the type of dendritic polymer recited in claims 2 and 26. However, a person skilled in the art would not have substituted a dendritic polymer of the '301 patent for a polyamine of the '893 patent, for the reasons set forth above.

With further respect to claims 2 and 26, the examiner's attention again is directed to the '893 patent, at column 10, lines 53-57, stating that the polyamine "*must contain*" at least one of a primary, secondary, or tertiary amino group, i.e., a nitrogen containing group. This should be compared to a dendritic polymer of the type recited in the claims 2 and 26, and utilized in the examples of the specification, i.e., BOLTORN H-40, and in the '062 publication, i.e., BOLTORN polyols, the structure of which is illustrated in previously provided Exhibit C. These dendritic polymers are not taught or suggested by the '893 patent. The '893 patent is silent with respect to the dendritic polymers recited in claims 2 and 26. The '893 patent polyamine *requires* amino-groups. The secondary reference provides no apparent reason to substitute a dendritic polymer of claims 2 and 26 (free of amino groups) for the polyamine of the '893 patent. In fact, such a substitution would destroy the teachings of the '893 patent. The explicit teachings of the '893 patent clearly teach persons skilled in the art away from any arguable substitution of a dendritic polymer of claim 2 or 26 for a polyamine of the '893 patent.

In particular, as discussed above, the '893 patent *requires* a polyamine containing amino groups. The dendritic polymer of the '301 patent, and those recited in claims 2 and 26, do *not* contain amino groups. Accordingly, substituting a dendritic polymer of the '301 patent for the polyamine of the '893 patent would destroy the teachings of the '893 patent. The '893 patent teaches away from such a substitution, and any contention that such a substitution would have been obvious in an obvious reconstruction of the claims.

In view of the above, because the '062 publication requires a dendritic polymer that further has been modified, because the '062 publication is directed to *inorganic hydrophobic* particles, as opposed to polymeric hydrophilic particles, because the polyamine of the '893 patent is different from a dendritic polymer, because the '893 patent fails to provide any teaching or suggestion that a dendritic polymer could be substituted for a polyamine, because of the unexpected and unpredicted results achieved by the claimed invention, and because of the additional reasons set forth above with respect to an essential polyamine required by the '893 patent, it is submitted that claims 2 and 26 would not have been obvious over a combination of the five references cited by the examiner, and that the rejection should be withdrawn.

Claims 16 and 17 stand rejected under 35 U.S.C. §103 as being obvious over the '893 patent in view of the '062 publication, the '466 patent, the '955 publication, and Goldman et al. U.S. Patent No. 5,562,646 ('646). Applicants traverse this rejection.

The patentability of the claims over the '863 patent, '062 publication, '466 patent, and '955 publication has been discussed above. Claims 16 and 17 recite preferred embodiments of the invention. The '646 patent does not overcome the deficiencies of the four references. The '646 patent is relied upon for teaching particles having a high SFC value. However, applicants do not rely solely upon the features of a high SFC value recited in claims 16 and 17 for patentability. Applicants do rely however upon all the features recited in claims 16 and 17, *and* in independent claim 1 from which they depend for patentability. Applicants have set forth reasoning why claim 1 is patentable over the cited references, and the '646 patent does not negate the patentability of independent claim 1. It is submitted therefore that claims 16 and 17 are patentable over the cited references for the same reasons independent claim 1 is patentable over these references, and that the rejection of these claims under 35 U.S.C. §103 should be withdrawn.

It is submitted that all claims are in a form and scope for allowance. An early and favorable action on the merits is respectfully requested.

Should the examiner wish to discuss the foregoing, or any matter of form in an effort to advance this application toward allowance, the examiner is urged to telephone the undersigned at the indicated number.

Dated: November 2, 2010

Respectfully submitted,

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US005599335A

**United States Patent** [19]

Goldman et al.

[11] **Patent Number:** **5,599,335**[45] **Date of Patent:** **Feb. 4, 1997**

[54] **ABSORBENT MEMBERS FOR BODY FLUIDS HAVING GOOD WET INTEGRITY AND RELATIVELY HIGH CONCENTRATIONS OF HYDROGEL-FORMING ABSORBENT POLYMER**

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[21] **Appl. No.:** 219,574

[22] **Filed:** Mar. 29, 1994

[51] **Int. Cl.<sup>6</sup>** ..... A61F 13/15; A61F 13/20

[52] **U.S. Cl.** ..... 604/368; 604/372; 604/378; 604/375

[58] **Field of Search** ..... 604/358, 367-369, 604/372, 374-376, 378, 381-382, 385.1; 428/327; 325/54.24, 54.26, 54.26, 329.4, 329.5

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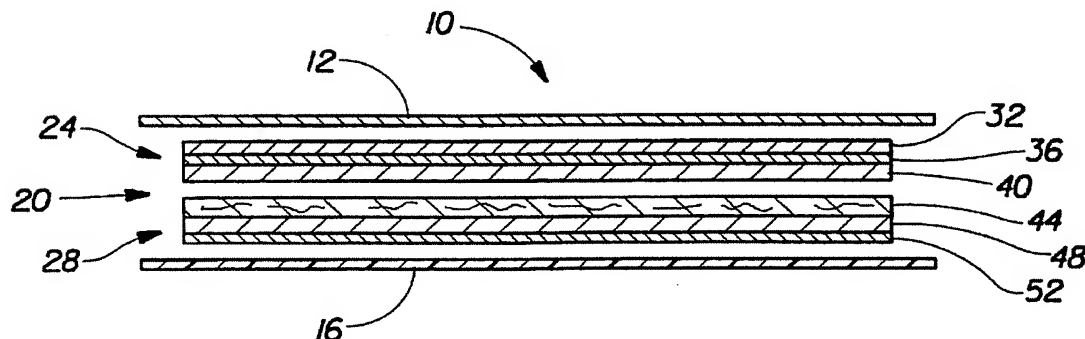
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[57]

**ABSTRACT**

Absorbent members useful in the containment of body fluids such as urine, that have at least one region containing hydrogel-forming absorbent polymer in a concentration of from about 60 to 100% by weight and providing a gel-continuous fluid transportation zone when in a swollen state. This hydrogel-forming absorbent polymer has: (a) a Saline Flow Conductivity (SFC) value of at least about  $30 \times 10^{-7}$  cm<sup>3</sup>/sec/g; (b) a Performance under Pressure (PUP) capacity value of at least about 23 g/g under a confining pressure of 0.7 psi (5 kPa); and (c) a basis weight of at least about 10 gsm. In addition, the region where this hydrogel-forming absorbent polymer is present has, even when subjected to normal use conditions, sufficient wet integrity such that the gel-continuous zone substantially maintains its ability to acquire and transport body fluids through the gel-continuous zone.

**40 Claims, 10 Drawing Sheets**

instances. However, AUL is inadequate for determining which hydrogel-forming absorbent polymers will provide the absorbency properties necessary so that the concentration of these polymers in absorbent structures can be increased without significant gel blocking or some other undesirable effect. It has been discovered that the permeability or flow conductivity of the hydrogel formed when these absorbent polymers swell in the presence of body fluids is extremely important to feasible inclusion of high concentrations of these absorbent polymers in localized regions or throughout the absorbent member. Differences in permeability or flow conductivity of the absorbent polymer can directly impact on the ability of the resultant hydrogel layer to acquire and distribute body fluids.

Indeed, certain of the hydrogel-forming absorbent polymers disclosed in U.S. Pat. Nos. 5,147,343 and 5,149,335 as having satisfactory AUL values will have inadequate permeability or flow conductivity to be useful at high concentrations in absorbent members. In order to have a high AUL value, it is only necessary that the hydrogel layer formed have at least minimal permeability such that, under a confining pressure of 0.3 psi, gel blocking does not occur to any significant degree. The degree of permeability needed to simply avoid gel blocking is much less than that needed to provide good fluid transportation properties. Hydrogel-forming absorbent polymers that avoid gel blocking can still be greatly deficient in these other fluid handling properties.

The permeability/flow conductivity of these hydrogel-forming absorbent polymers can be defined in terms of their Saline Flow Conductivity (SFC) values. SFC measures the ability of a material to transport saline fluids, such as the ability of the hydrogel layer formed from the swollen hydrogel-forming absorbent polymer to transport body fluids. A good example of a material having relatively a high SFC value is an air-laid web of wood-pulp fibers. Typically, an air-laid web of pulp fibers (e.g. having a density of 0.15 g/cc) will exhibit an SFC value of about  $200 \times 10^{-7} \text{ cm}^3 \text{ sec/g}$ . By contrast, typical hydrogel-forming absorbent polymers such as Aqualic L-74 (made by Nippon Shokubai Co., LTD) and Nalco-1180 (made by Nalco Chemical Co.) exhibit SFC values of at most  $1 \times 10^{-7} \text{ cm}^3 \text{ sec/g}$ . Accordingly, it would be highly desirable to be able to use hydrogel-forming absorbent polymers that more closely approach an air-laid web of wood pulp fibers in terms of SFC. This is particularly true if higher, localized concentrations of these hydrogel-forming absorbent polymers are to be effectively used in the absorbent member. (Higher SFC values also are reflective of the ability of the resultant hydrogel to acquire body fluids under normal usage conditions.)

Another problem with using AUL values measured according to U.S. Pat. Nos. 5,147,343 and 5,149,335 is that they do not reflect all of the potential pressures that can be operative on the hydrogel-forming polymer in the absorbent structure. As noted above, AUL is measured in these patents at a pressure of about 0.3 psi. It is believed that a much higher confining pressure of about 0.7 psi more adequately reflects the full range of localized mechanical pressures (e.g., sitting, sleeping, squatting, taping, elastics, leg motions, other tension and torsional motions) on an absorbent structure. See U.S. Pat. No. 5,147,345 (Young et al), issued Sep. 15, 1992. Additionally, many of the absorbent structures that comprise these hydrogel-forming absorbent polymers can include other components, such as an acquisition layer that receives the initial discharge of body fluids. See, for example, U.S. Pat. No. 4,673,402 (Weisman et al), issued Jun. 16, 1987 and U.S. Pat. No. 4,935,022 (Lash et al), issued Jun. 19, 1990. This acquisition layer can comprise

fibers, such as certain chemically stiffened fibers, that have a relatively high capillary suction. See, for example, U.S. Pat. No. 5,217,445 (Young et al), issued Jun. 8, 1993. To take into account these additional capillary pressures that could affect fluid acquisition by these hydrogel-forming absorbent polymers, it is more realistic to measure demand absorbency performance under a higher pressure, i.e., about 0.7 psi. This would take into better account not only the localized mechanical pressures exerted during use, but also the additional capillary pressures resulting from other components (e.g., acquisition layer) present in the absorbent structure.

Another factor that has to be considered in order to take full advantage of the permeability/flow conductivity of the hydrogel layer formed from these absorbent polymers is the wet integrity of the region or regions in the absorbent member that comprise these polymers. For hydrogel-forming absorbent polymers having relatively high SFC values, it is extremely important that the region(s) in which polymers are present have good wet integrity. By "good wet integrity" is meant that the region or regions in the absorbent member having the high concentration of hydrogel-forming absorbent polymer have sufficient integrity in a dry, partially wet, and/or wetted state such that the physical continuity (and thus the capability of acquiring and transporting fluid through contiguous interstitial voids/capillaries) of the hydrogel formed upon swelling in the presence of body fluids is not substantially disrupted or altered, even when subjected to normal use conditions. During normal use, absorbent cores in absorbent articles are typically subjected to tensional and torsional forces of varying intensity and direction. These tensional and torsional forces include bunching in the crotch area, stretching and twisting forces as the person wearing the absorbent article walks, squats, bends, and the like. If wet integrity is inadequate, these tensional and torsional forces can potentially cause a substantial alteration and/or disruption in the physical continuity of the hydrogel such that its capability of transporting fluids through the contiguous voids and capillaries is degraded, e.g., the hydrogel layer can be partially separated, fully separated, have gaps introduced, have areas that are significantly thinned, and/or broken up into a plurality of significantly smaller segments. Such alteration could minimize or completely negate any advantageous permeability/flow conductivity properties of the hydrogel-forming absorbent polymer.

Accordingly, it would be desirable to be able to provide an absorbent member comprising: (1) a region or regions having a relatively high concentration of hydrogel-forming absorbent polymer; (2) with permeability/flow conductivity properties more like an air-laid fibrous web; (3) that can readily acquire fluids from even high capillary suction acquisition layers under typical usage pressures; (4) in a matrix that provides sufficient wet integrity such that its capability for acquiring and transporting fluids is not substantially reduced or minimized, even when subjected to normal use forces.

#### DISCLOSURE OF THE INVENTION

The present invention relates to absorbent members useful in the containment of body fluids such as urine. These absorbent members comprise at least one region having hydrogel-forming absorbent polymer in a concentration of from about 60 to 100% by weight and providing a gel-continuous fluid transportation zone when in a swollen state. This hydrogel-forming absorbent polymer has:



degradation in other hydrogel-forming absorbent polymer properties such as Performance Under Pressure (PUP) capacity and level of extractable polymer. Thus, for example, it can be useful to use a size cut having a mass median size in the range of from about 500 to about 710 microns wherein only minimal mass fractions of the particulates have sizes either greater than about 710 microns or less than about 500 microns. Alternatively, a broader size cut wherein the particles generally have a size in the range of from about 300 microns to about 800 microns can be useful.

## b. Physical Properties

### (1). Saline Flow Conductivity (SFC)

An important characteristic of the hydrogel-forming absorbent polymers useful in the present invention is their permeability or flow conductivity when swollen with body fluids so as to form a hydrogel zone or layer. This permeability or flow conductivity is defined herein in terms of the Saline Flow Conductivity (SFC) value of the hydrogel-forming absorbent polymer. SFC measures the ability of the formed hydrogel zone or layer to transport or distribute body fluids under usage pressures. It is believed that when a hydrogel-forming absorbent polymer is present at high concentrations in an absorbent member and then swells to form a hydrogel under usage pressures, the boundaries of the hydrogel come into contact, and interstitial voids in this high-concentration region become generally bounded by hydrogel. When this occurs, it is believed the permeability or flow conductivity properties of this region are generally reflective of the permeability or flow conductivity properties of a hydrogel zone or layer formed from the hydrogel-forming absorbent polymer alone. It is further believed that increasing the permeability of these swollen high-concentration regions to levels that approach or even exceed conventional acquisition/distribution materials, such as wood-pulp fluff, can provide superior fluid handling properties for the absorbent member and absorbent core, thus decreasing incidents of leakage, especially at high fluid loadings. (Higher SFC values also are reflective of the ability of the formed hydrogel to acquire body fluids under normal usage conditions.)

The SFC value of the hydrogel-forming absorbent polymers useful in the present invention is at least about  $30 \times 10^{-7}$  cm<sup>3</sup>sec/g, preferably at least about  $50 \times 10^{-7}$  cm<sup>3</sup>sec/g, and most preferably at least about  $100 \times 10^{-7}$  cm<sup>3</sup>sec/g. Typically, these SFC values are in the range of from about 30 to about  $1000 \times 10^{-7}$  cm<sup>3</sup>sec/g, more typically from about 50 to about  $500 \times 10^{-7}$  cm<sup>3</sup>sec/g, and most typically from about 100 to about  $350 \times 10^{-7}$  cm<sup>3</sup>sec/g. A method for determining the SFC value of these hydrogel-forming absorbent polymers is provided hereafter in the Test Method Section.

### (2). Performance Under Pressure (PUP)

Another important characteristic of the hydrogel-forming absorbent polymers useful in the present invention is their demand absorbency capacity under a high confining pressure. This demand-absorbency capacity is defined in terms of the polymer's Performance Under Pressure (PUP) capacity. PUP capacity measures the ability of a high basis weight zone or layer of the hydrogel-forming absorbent polymer to absorb body fluids under usage pressures. When a hydrogel-forming absorbent polymer is incorporated into an absorbent member at high concentrations, the polymer needs to be capable of absorbing large quantities of body fluids in a

reasonable time period under usage pressures. Otherwise, the absorbent member will be less effective at absorbing fluid, e.g., by partitioning fluid from acquisition components that provide temporary holding capacity for this fluid. When this occurs, it is believed that the absorbent core is left with insufficient temporary holding capacity to contain subsequent gushes of body fluid and can leak prematurely. Also, to be able to deliver a high storage capacity from an absorbent core of minimal weight and thickness, the hydrogel-forming absorbent polymer needs to have a relatively high PUP capacity. A relatively high PUP capacity hydrogel-forming polymer is also needed to provide economical absorbent cores.

Usage pressures exerted on the hydrogel-forming absorbent polymer include both mechanical pressures (e.g., exerted by the weight and motions of the user, taping forces, etc.) and capillary pressures (e.g., resulting from the acquisition component(s) in the absorbent core that temporarily hold fluid before it is absorbed by the hydrogel-forming absorbent polymer.) It is believed that a total pressure of about 0.7 psi (5 kPa) is reflective of the sum of these pressures on the hydrogel-forming absorbent polymer as it absorbs body fluids under usage conditions.

The PUP capacity of hydrogel-forming absorbent polymers useful in the present invention is generally at least about 23 g/g, preferably at least about 25 g/g, and most preferably at least about 29 g/g. Typically, these PUP capacity values are in the range of from about 23 to about 35 g/g, more typically from about 25 to about 33 g/g, and most typically from about 29 to about 33 g/g. A method for determining the PUP capacity value of these hydrogel-forming absorbent polymers is provided hereafter in the Test Method Section.

### (3). Extractable Polymer

Another important characteristic of hydrogel-forming absorbent polymers useful in the present invention is the level of extractable polymer material present therein. See U.S. Pat. No. 4,654,039 (Brandt et al), issued Mar. 31, 1987 (reissued Apr. 19, 1988 as Re. 32,649). Many hydrogel-forming absorbent polymers contain significant levels of extractable polymer material. This extractable polymer material can be leached out from the resultant hydrogel by body fluids (e.g., urine) during the time period such body fluids remain in contact with the hydrogel-forming absorbent polymer. It is believed such extracted polymer material can alter both the chemical characteristics (e.g., osmolarity) and physical characteristics (e.g., viscosity) of the body fluid to such an extent that the fluid is more slowly absorbed and more poorly held by the hydrogel. This polymer contaminated fluid is also more poorly transported through the absorbent member. Such a situation can contribute to undesirable and premature leakage of body fluid from the absorbent article. Thus it is desirable to use hydrogel-forming absorbent polymers with lower levels of extractable polymer material.

The importance of not adversely impacting the effective absorption/retention of body fluids by the swollen hydrogel-forming absorbent polymer, or the facile transport of body fluids through regions of the absorbent member containing the swollen polymer, is believed to be particularly true as: (a) the quantity of polymer in the absorbent member is increased; (b) the quantities of other absorbent components (e.g., fibers) are decreased; and/or (c) the localized concentration of polymer in the absorbent member is increased.

backsheet are joined directly to each other at the periphery thereof. The topsheet and backsheet can also be indirectly joined together by directly joining them to the absorbent core by the attachment means.

The backsheet is typically impervious to body fluids and is preferably manufactured from a thin plastic film, although other flexible fluid impervious materials may also be used. As used herein, the term "flexible" refers to materials that are compliant and will readily conform to the general shape and contours of the human body. The backsheet prevents body fluids absorbed and contained in the absorbent core from wetting articles that contact the such as pants, pajamas, undergarments, and the like. The backsheet can comprise a woven or nonwoven material, polymeric films such as thermoplastic films of polyethylene or polypropylene, or composite materials such as a film-coated nonwoven material. Preferably, the backsheet is a polyethylene film having a thickness of from about 0.012 mm (0.5 mil) to about 0.051 mm (2.0 mils). Exemplary polyethylene films are manufactured by Clopay Corporation of Cincinnati, Ohio, under the designation P 18-0401 and by Ethyl Corporation, Visqueen Division, of Terre Haute, Ind., under the designation XP-39385. The backsheet is preferably embossed and/or matte finished to provide a more clothlike appearance. Further, the backsheet can permit vapors to escape from the absorbent core (i.e., breathable) while still preventing body fluids from passing through the backsheet.

The topsheet is compliant, soft feeling, and non-irritating to the wearer's skin. Further, the topsheet is fluid pervious permitting body fluids to readily penetrate through its thickness. A suitable topsheet can be manufactured from a wide range of materials such as woven and nonwoven materials; polymeric materials such as apertured formed thermoplastic films, apertured plastic films, and hydroformed thermoplastic films; porous foams; reticulated foams; reticulated thermoplastic films; and thermoplastic scrims. Suitable woven and nonwoven materials can be comprised of natural fibers (e.g., wood or cotton fibers), synthetic fibers (e.g., polymeric fibers such as polyester, polypropylene, or polyethylene fibers) or from a combination of natural and synthetic fibers.

Preferred topsheets for use in absorbent articles of the present invention are selected from high loft nonwoven topsheets and aperture formed film topsheets. Apertured formed films are especially preferred for the topsheet because they are pervious to body fluids and yet non-absorbent and have a reduced tendency to allow fluids to pass back through and rewet the wearer's skin. Thus, the surface of the formed film that is in contact with the body remains dry, thereby reducing body soiling and creating a more comfortable feel for the wearer. Suitable formed films are described in U.S. Pat. No. 3,929,135 (Thompson), issued Dec. 30, 1975; U.S. Pat. No. 4,324,246 (Mullane, et al.), issued Apr. 13, 1982; U.S. Pat. No. 4,342,314 (Radel, et al.), issued Aug. 3, 1982; U.S. Pat. No. 4,463,045 (Ahr et al.), issued Jul. 31, 1984; and U.S. Pat. No. 5,006,394 (Baird), issued Apr. 9, 1991. Each of these patents are incorporated herein by reference. Particularly preferred microapertured formed film topsheets are disclosed in U.S. Pat. No. 4,609,518 (Curro et al), issue Sep. 2, 1986 and U.S. Pat. No. 4,629,643 (Curro et al), issued Dec. 16, 1986, which are incorporated by reference. The preferred topsheet for use in catamenial products of the present invention is the formed film described in one or more of the above patents and marketed on sanitary napkins by The Procter & Gamble Company of Cincinnati, Ohio as "DRI-WEAVE®."

The body surface of the formed film topsheet can be hydrophilic so as to help body fluids to transfer through the

topsheet faster than if the body surface was not hydrophilic so as to diminish the likelihood that fluid will flow off the topsheet rather than flowing into and being absorbed by the absorbent structure. In a preferred embodiment, surfactant is incorporated into the polymeric materials of the formed film topsheet such as is described in U.S. patent application Ser. No. 07/794,745, "Absorbent Article Having A Nonwoven and Apertured Film Coversheet" filed on Nov. 19, 1991 by Aziz, et al., which is incorporated by reference. Alternatively, the body surface of the topsheet can be made hydrophilic by treating it with a surfactant such as is described in the above referenced U.S. Pat. No. 4,950,254, incorporated herein by reference.

#### F. Test Methods

##### 1. Saline Flow Conductivity (SFC)

This test determines the Saline Flow Conductivity (SFC) of the gel layer formed from hydrogel-forming absorbent polymer that is swollen in Jayco synthetic urine under a confining pressure. The objective of this test is to assess the ability of the hydrogel layer formed from a hydrogel-forming absorbent polymer to acquire and distribute body fluids when the polymer is present at high concentrations in an absorbent member and exposed to usage mechanical pressures. Darcy's law and steady-state flow methods are used for determining saline flow conductivity. (See, for example, "Absorbency," ed. by P. K. Chatterjee, Elsevier, 1985, Pages 42-43 and "Chemical Engineering Vol. II, Third Edition, J. M. Coulson and J. F. Richardson, Pergamon Press, 1978, Pages 125-127.)

The hydrogel layer used for SFC measurements is formed by swelling a hydrogel-forming absorbent polymer in Jayco synthetic urine for a time period of 60 minutes. The hydrogel layer is formed and its flow conductivity measured under a mechanical confining pressure of 0.3 psi (about 2 kPa). Flow conductivity is measured using a 0.118M NaCl solution. For a hydrogel-forming absorbent polymer whose uptake of Jayco synthetic urine versus time has substantially leveled off, this concentration of NaCl has been found to maintain the thickness of the hydrogel layer substantially constant during the measurement. For some hydrogel-forming absorbent polymers, small changes in hydrogel-layer thickness can occur as a result of polymer swelling, polymer deswelling, and/or changes in hydrogel-layer porosity. A constant hydrostatic pressure of 4920 dyne/cm<sup>2</sup> (5 cm of 0.118M NaCl) is used for the measurement.

Flow rate is determined by measuring the quantity of solution flowing through the hydrogel layer as a function of time. Flow rate can vary over the duration of the measurement. Reasons for flow-rate variation include changes in the thickness of the hydrogel layer and changes in the viscosity of interstitial fluid, as the fluid initially present in interstitial voids (which, for example, can contain dissolved extractable polymer) is replaced with NaCl solution. If flow rate is time dependent, then the initial flow rate, typically obtained by extrapolating the measured flow rates to zero time, is used to calculate flow conductivity. The saline flow conductivity is calculated from the initial flow rate, dimensions of the hydrogel layer, and hydrostatic pressure. For systems where the flow rate is substantially constant, a hydrogel-layer permeability coefficient can be calculated from the saline flow conductivity and the viscosity of the NaCl solution.

A suitable apparatus 610 for this test is shown in FIG. 7. This apparatus includes a constant hydrostatic head reservoir indicated generally as 612 that sits on a laboratory jack

indicated generally as 614. Reservoir 612 has lid 616 with a stoppered vent indicated by 618 so that additional fluid can be added to reservoir 612. An open-ended tube 620 is inserted through lid 616 to allow air to enter reservoir 612 for the purpose of delivering fluid at a constant hydrostatic pressure. The bottom end of tube 620 is positioned so as to maintain fluid in cylinder 634 at a height of 5.0 cm above the bottom of hydrogel layer 668 (see FIG. 8).

Reservoir 612 is provided with a generally L-shaped delivery tube 622 having an inlet 622a that is below the surface of the fluid in the reservoir. The delivery of fluid by tube 622 is controlled by stopcock 626. Tube 622 delivers fluid from reservoir 612 to a piston/cylinder assembly generally indicated as 628. Beneath assembly 628 is a support screen (not shown) and a collection reservoir 630 that sits on a laboratory balance 632.

Referring to FIG. 7, assembly 628 basically consists of a cylinder 634, a piston generally indicated as 636 and a cover 637 provided with holes for piston 636 and delivery tube 622. As shown in FIG. 7, the outlet 622b of tube 622 is positioned below the bottom end of tube 620 and thus will also be below the surface of the fluid (not shown) in cylinder 634. As shown in FIG. 8, piston 636 consists of a generally cylindrical LEXAN® shaft 638 having a concentric cylindrical hole 640 bored down the longitudinal axis of the shaft. Both ends of shaft 638 are machined to provide ends 642 and 646. A weight indicated as 648 rests on end 642 and has a cylindrical hole 648a bored through the center thereof.

Inserted on the other end 646 is a generally circular Teflon piston head 650 having an annular recess 652 in the bottom thereof. Piston head 650 is sized so as to slidably move inside cylinder 634. As particularly shown in FIG. 9, piston head 650 is provided with four concentric rings of twenty-four cylindrical holes each indicated generally as 654, 656, 658, and 660. As can be seen in FIG. 9, concentric rings 654 to 660 fit within the area defined by recess 652. The holes in each of these concentric rings are bored from the top to bottom of piston head 650. The holes in each ring are spaced by approximately 15 degrees and offset by approximately 7.5 degrees from the holes in adjacent rings. The holes in each ring have a progressively smaller diameter going inwardly from ring 654 (0.204 inch diameter) to ring 660 (0.111 inch diameter). Piston head 650 also has cylindrical hole 662 bored in the center thereof to receive end 646 of shaft 638.

As shown in FIG. 8, a fritted circular glass disc 664 fits within recess 652. Attached to bottom end of cylinder 634 is a No. 400 mesh stainless steel cloth screen 666 that is biaxially stretched to tautness prior to attachment. The sample of hydrogel-forming absorbent polymer indicated as 668 is supported on screen 666.

Cylinder 634 is bored from a transparent LEXAN® rod or equivalent and has an inner diameter of 6.00 cm (area=28.27 cm<sup>2</sup>), a wall thickness of approximately 0.5 cm, and a height of approximately 6.0 cm. Piston head 650 is machined from a solid Teflon rod. It has a height of 0.625 inches and a diameter that is slightly less than the inner diameter of cylinder 634, so that it fits within the cylinder with minimum wall clearances, but still slides freely. Recess 652 is approximately 56 mm in diameter by 4 mm deep. Hole 662 in the center of the piston head 650 has a threaded 0.625 inch opening (18 threads/inch) for end 646 of shaft 638. Fritted disc 664 is chosen for high permeability (e.g., Chemglass Cat No. CG-201-40, 60 mm diameter; X-Coarse Porosity) and is ground so that it fits snugly within recess 652 of piston head 650, with the bottom of the disc being flush with the

bottom of the piston head. Shaft 638 is machined from a LEXAN® rod and has an outer diameter of 0.875 inches and an inner diameter of 0.250 inches. End 646 is approximately 0.5 inches long and is threaded to match hole 662 in piston head 650. End 642 is approximately an inch long and 0.623 inches in diameter, forming an annular shoulder to support the stainless steel weight 648. Fluid passing through the hole 640 in shaft 638 can directly access the fritted disc 664. The annular stainless steel weight 648 has an inner diameter of 0.625 inches, so that it slips onto end 642 of shaft 638 and rests on the annular shoulder formed therein. The combined weight of fitted glass disc 664, piston 636 and weight 648 equals 596 g, which corresponds to a pressure of 0.3 psi for an area of 28.27 cm<sup>2</sup>. Cover 637 is machined from LEXAN® or its equivalent and is dimensioned to cover the top of cylinder 634. It has an 0.877 inch opening in the center thereof for shaft 638 of piston 636 and a second opening near the edge thereof for delivery tube 622.

The cylinder 634 rests on a 16 mesh rigid stainless steel support screen (not shown) or equivalent. This support screen is sufficiently permeable so as to not impede fluid flow into the collection reservoir 630. The support screen is generally used to support cylinder 634 when the flow rate of saline solution through assembly 628 is greater than about 0.02 g/sec. For flow rates less than about 0.02 g/sec, it is preferable that there be a continuous fluid path between cylinder 634 and the collection reservoir. This can be accomplished by replacing the support screen, collection reservoir 630, and analytical balance 632 with analytical balance 716, reservoir 712, fritted funnel 718, and the respective connecting tubes and valves of apparatus 710 (see FIG. 10), and positioning cylinder 634 on the fritted disc in fritted funnel 718.

Jayco synthetic urine used in this method is prepared by dissolving a mixture of 2.0 g KCL, 2.0 g Na<sub>2</sub>SO<sub>4</sub>, 0.85 g NH<sub>4</sub>H<sub>2</sub>PO<sub>4</sub>, 0.15 g (NH<sub>4</sub>)<sub>2</sub>HPO<sub>4</sub>, 0.19 g CaCl<sub>2</sub>, and 0.23 g MgCl<sub>2</sub> to 1.0 liters with distilled water. The salt mixture can be purchased from Endovations, Reading, Pa. (cat No. JA-00131-000-01).

The 0.118M NaCl solution is prepared by dissolving 6.896 g NaCl (Baker Analyzed Reagent or equivalent) to 1.0 liters with distilled water.

An analytical balance 632 accurate to 0.01 g (e.g., Mettler PM4000 or equivalent) is typically used to measure the quantity of fluid flowing through the hydrogel layer 668 when the flow rate is about 0.02 g/sec or greater. A more accurate balance (e.g., Mettler AE200 or equivalent) can be needed for less permeable hydrogel layers having lower flow rates. The balance is preferably interfaced to a computer for monitoring fluid quantity versus time.

The thickness of hydrogel layer 668 in cylinder 634 is measured to an accuracy of about 0.1 mm. Any method having the requisite accuracy can be used, as long as the weights are not removed and the hydrogel layer is not additionally compressed or disturbed during the measurement. Using a caliper gauge (e.g., Manostat 15-100-500 or equivalent) to measure the vertical distance between the bottom of the stainless steel weight 648 and the top of cover 637, relative to this distance with no hydrogel layer 668 in cylinder 634 is acceptable. Also acceptable is the use of a depth gauge (e.g., Ono Sokki EG-225 or equivalent) to measure the position of piston 636 or stainless steel weight 648 relative to any fixed surface, compared to its position with no hydrogel layer in cylinder 634.

The SFC measurement is performed at ambient temperature (i.e., 20°-25° C.) and is carried out as follows:

0.9 gm aliquot of hydrogel-forming absorbent polymer (corresponding to a basis weight of 0.032 gm/cm<sup>2</sup>) is added to cylinder 634 and distributed evenly on screen 666. For most hydrogel-forming absorbent polymers, moisture content is typically less than 5%. For these, the quantity of hydrogel-forming absorbent polymer to be added can be determined on a wet-weight (as is) basis. For hydrogel-forming absorbent polymers having a moisture content greater than about 5%, the added polymer weight should be corrected for moisture (i.e., the added polymer should be 0.9 g on a dry-weight basis). Care is taken to prevent hydrogel-forming absorbent polymer from adhering to the cylinder walls. Piston 636 (minus weight 648) with disc 664 positioned in recess 652 of piston head 650 is inserted into cylinder 634 and positioned on top of the dry hydrogel-forming absorbent polymer 668. If necessary, piston 636 can be turned gently to more-uniformly distribute the hydrogel-forming absorbent polymer on screen 666. Cylinder 634 is then covered with cover 637 and weight 648 is then positioned on end 642 of shaft 638.

A fritted disc (coarse or extra coarse) having a diameter greater than that of cylinder 634 is positioned in a wide/shallow flat-bottomed container that is filled to the top of the fritted disc with Jayco synthetic urine. The piston/cylinder assembly 628 is then positioned on top of this fritted glass disc. Fluid from the container passes through the fritted disc and is absorbed by the hydrogel-forming absorbent polymer 668. As the polymer absorbs fluid, a hydrogel layer is formed in cylinder 634. After a time period of 60 minutes, the thickness of the hydrogel layer is determined. Care is taken that the hydrogel layer does not lose fluid or take in air during this procedure.

The piston/cylinder assembly 628 is then transferred to apparatus 610. The support screen (not shown) and any gap between it and the piston/cylinder assembly 628 is presaturated with saline solution. If the fritted funnel 718 of the PUP apparatus 710 is used to support cylinder 634, the surface of the fritted funnel should be minimally elevated relative to the height of the fluid in the collection reservoir, with valves between the fritted funnel and the collection reservoir being in the open position. (The fritted funnel elevation should be sufficient such that fluid passing through the hydrogel layer does not accumulate in the funnel.)

The SFC measurement is initiated by adding NaCl solution through hole 640 in shaft 638 in order to expel air from piston head 650 and then turning stopcock 626 to an open position so that delivery tube 622 delivers fluid to cylinder 634 to a height of 5.0 cm above the bottom of hydrogel layer 668. Although the measurement is considered to have been initiated ( $t_0$ ) at the time NaCl solution is first added, the time at which a stable hydrostatic pressure, corresponding to 5.0 cm of saline solution, and a stable flow rate is attained ( $t_1$ ) is noted. (The time  $t_1$  should typically be about one minute or less.) The quantity of fluid passing through hydrogel layer 668 versus time is determined gravimetrically for a time period of 10 minutes. After the elapsed time, piston/cylinder assembly 628 is removed and the thickness of hydrogel layer 668 is measured. Generally the change in thickness of the hydrogel layer is less than about 10%.

In general, flow rate need not be constant. The time-dependent flow rate through the system,  $F_p(t)$  is determined, in units of g/sec, by dividing the incremental weight of fluid passing through the system (in grams) by incremental time (in seconds). Only data collected for times between  $t_1$  and 10 minutes is used for flow rate calculations. Flow rate results between  $t_1$  and 10 minutes is used to calculate a value for  $F_p(t=0)$ , the initial flow rate through the hydrogel layer.

$F_p(t=0)$  is calculated by extrapolating the results of a least-squares fit of  $F_p(t)$  versus time to  $t=0$ .

For a layer having a very high permeability (e.g., a flow rate greater than ~2 g/sec), it may not be practical to collect fluid for the full 10 minute time period. For flow rates greater than ~2 g/sec, the time of collection can be shortened in proportion to the flow rate.

For some hydrogel-forming absorbent polymers having extremely low permeability, absorption of fluid by the hydrogel competes with transport of fluid through the hydrogel layer and either there is no flow of fluid through the hydrogel layer and into the reservoir or, possibly, there is a net absorption of fluid out of the PUP reservoir. For these extremely low permeability hydrogel layers, it is optional to extend the time for Jayco SynUrine absorption to longer periods (e.g., 16 hours).

In a separate measurement, the flow rate through apparatus 610 and the piston/cylinder assembly 628 ( $F_a$ ) is measured as described above, except that no hydrogel layer is present. If  $F_a$  is much greater than the flow rate through the system when the hydrogel layer is present,  $F_p$ , then no correction for the flow resistance of the SFC apparatus and the piston/cylinder assembly is necessary. In this limit,  $F_p = F_a$ , where  $F_p$  is the contribution of the hydrogel layer to the flow rate of the system. However if this requirement is not satisfied, then the following correction is used to calculate the value of  $F_p$  from the values of  $F_p$  and  $F_a$ :

$$F_p = (F_a \times F_p) / (F_a - F_p)$$

The Saline Flow Conductivity (K) of the hydrogel layer is calculated using the following equation:

$$K = (F_p(t=0) \times L_0) / (\rho \times A \times \Delta P)$$

where  $F_p(t=0)$  is the flow rate in g/sec determined from regression analysis of the flow rate results and any correction due to assembly/apparatus flow resistance,  $L_0$  is the initial thickness of the hydrogel layer in cm,  $\rho$  is the density of the NaCl solution in gm/cm<sup>3</sup>, A is the area of the hydrogel layer in cm<sup>2</sup>,  $\Delta P$  is the hydrostatic pressure in dyne/cm<sup>2</sup>, and the saline flow conductivity, K, is in units of cm<sup>3</sup>sec/gm.

The average of three determinations should be reported.

For hydrogel layers where the flow rate is substantially constant, a permeability coefficient ( $\kappa$ ) can be calculated from the saline flow conductivity using the following equation:

$$\kappa = K \eta$$

where  $\eta$  is the viscosity of the NaCl solution in poise and the permeability coefficient,  $\kappa$ , is in units of cm<sup>2</sup>.

The following is an example of how SFC is calculated according to the present invention:

The measured value of  $F_a$  is 412 g/min=6.87 g/sec. For a single determination on the particulate hydrogel-forming polymer sample 3-5 (Example 3), the extrapolated value for  $F_p(t=0)$  is 33.9 g/min=0.565 g/sec, with a very-low ratio of slope:intercept of  $9 \times 10^{-3}$  sec<sup>-1</sup>. Correcting for apparatus resistance:

$$F_p = (6.87 \times 0.565) / (6.87 - 0.565) = 0.616 \text{ g/sec}$$

Given a 0.118M saline density of 1.003 g/cm<sup>3</sup> (CRC Handbook of Chemistry and Physics, 61st Edition) a hydrogel-layer thickness of 1.134 cm, a hydrogel layer area of 28.27 cm<sup>2</sup>, and a hydrostatic pressure of 4920 dyne/cm<sup>2</sup>.

$$K = (0.616 \times 1.134) / (1.003 \times 28.27 \times 4920) = 5.0 \times 10^{-6} \text{ cm}^3 \text{sec/gm}$$

Considering the substantially constant flow rate and given a 0.118M saline viscosity of 0.01015 poise (CRC Handbook of Chemistry and Physics, 61st Edition):

$$\kappa = K\eta = (5.0 \times 10^{-6}) \times 0.01015 = 5.1 \times 10^{-8} \text{ cm}^2$$

## 2. Performance Under Pressure (PUP) Capacity

This test determines the 60 minute gram/gram absorption of synthetic urine for a hydrogel-forming absorbent polymer that is laterally confined in a piston/cylinder assembly under a confining pressure of 0.7 psi (about 5 kPa). The objective of the test is to assess the ability of a hydrogel-forming absorbent polymer layer to absorb body fluids, over a practical period of time, when the polymer is present at high basis weight and high concentrations in an absorbent member and exposed to usage pressures. Usage pressures against which a hydrogel-forming polymer is forced to absorb urine against include mechanical pressures resulting from the weight and/or motions of the wearer, mechanical pressures resulting from elastics and fastening systems, and the hydrostatic suction resulting from adjacent capillary (e.g., fibrous) layers and/or structures as they are drained of fluid.

The test fluid for the PUP capacity test is Jayco synthetic urine. This fluid is absorbed by the hydrogel-forming absorbent polymer under demand absorption conditions at near-zero hydrostatic pressure.

A suitable apparatus 710 for this test is shown in FIG. 10. At one end of this apparatus is a fluid reservoir 712 (such as a petri dish) having a cover 714. Reservoir 712 rests on an analytical balance indicated generally as 716. The other end of apparatus 710 is a fritted funnel indicated generally as 718, a piston/cylinder assembly indicated generally as 720 that fits inside funnel 718, and cylindrical plastic fritted funnel cover indicated generally as 722 that fits over funnel 718 and is open at the bottom and closed at the top, the top having a pinhole. Apparatus 710 has a system for conveying fluid in either direction that consists of sections glass capillary tubing indicated as 724 and 731a, flexible plastic tubing (e.g., 1/4 inch i.d. and 3/8 inch o.d. Tygon tubing) indicated as 731b, stopcock assemblies 726 and 738 and Teflon connectors 748, 750 and 752 to connect glass tubing 724 and 731a and stopcock assemblies 726 and 738. Stopcock assembly 726 consists of a 3-way valve 728, glass capillary tubing 730 and 734 in the main fluid system, and a section of glass capillary tubing 732 for replenishing reservoir 712 and forward flushing the fritted disc in fritted funnel 718. Stopcock assembly 738 similarly consists of a 3-way valve 740, glass capillary tubing 742 and 746 in the main fluid line, and a section of glass capillary tubing 744 that acts as a drain for the system.

Referring to FIG. 11, assembly 720 consists of a cylinder 754, a cup-like piston indicated by 756 and a weight 758 that fits inside piston 756. Attached to bottom end of cylinder 754 is a No. 400 mesh stainless steel cloth screen 759 that is biaxially stretched to tautness prior to attachment. Hydrogel-forming absorbent polymer indicated generally as 760 rests on screen 759. Cylinder 754 is bored from a transparent LEXAN® rod (or equivalent) and has an inner diameter of 6.00 cm (area=28.27 cm<sup>2</sup>), with a wall thickness of approximately 5 mm and a height of approximately 5 cm. The piston 756 is in the form of a Teflon cup and is machined to fit into cylinder 754 within tight tolerances. Cylindrical stainless steel weight 758 is machined to fit snugly within piston 756 and is fitted with a handle on the top (not shown) for ease in removing. The combined weight of piston 756 and weight

758 is 1390 g, which corresponds to a pressure of 0.7 psi for an area of 28.27 cm<sup>2</sup>.

The components of apparatus 710 are sized such that the flow rate of synthetic urine therethrough, under a 10 cm hydrostatic head, is at least 0.01 g/cm<sup>2</sup>/sec, where the flow rate is normalized by the area of fritted funnel 718. Factors particularly impactful on flow rate are the permeability of the fritted disc in fritted funnel 718 and the inner diameters of glass tubing 724, 730, 734, 742, 746 and 731a, and stopcock valves 728 and 740.

Reservoir 712 is positioned on an analytical balance 716 that is accurate to at least 0.01 g with a drift of less than 0.1 g/hr. The balance is preferably interfaced to a computer with software that can (i) monitor balance weight change at pre-set time intervals from the initiation of the PUP test and (ii) be set to auto initiate on a weight change of 0.01–0.05 g, depending on balance sensitivity. Capillary tubing 724 entering the reservoir 712 should not contact either the bottom thereof or cover 714. The volume of fluid (not shown) in reservoir 712 should be sufficient such that air is not drawn into capillary tubing 724 during the measurement. The fluid level in reservoir 712, at the initiation of the measurement, should be approximately 2 mm below the top surface of fritted disc in fritted funnel 718. This can be confirmed by placing a small drop of fluid on the fritted disc and gravimetrically monitoring its slow flow back into reservoir 712. This level should not change significantly when piston/cylinder assembly 720 is positioned within funnel 718. The reservoir should have a sufficiently large diameter (e.g., ~14 cm) so that withdrawal of ~40 ml portions results in a change in the fluid height of less than 3 min.

Jayco synthetic urine used in this test is prepared by dissolving a mixture of 2.0 g KCl, 2.0 g Na<sub>2</sub>SO<sub>4</sub>, 0.85 g NH<sub>4</sub>H<sub>2</sub>PO<sub>4</sub>, 0.15 g (NH<sub>4</sub>)<sub>2</sub>HPO<sub>4</sub>, 0.19 g CaCl<sub>2</sub>, and 0.23 g MgCl<sub>2</sub> to 1.0 liters with distilled water. The salt mixture can be purchased from Endovations, Reading, Pa. (cat no. JA-00131-000-01).

Prior to measurement, the assembly is filled with synthetic urine. The fritted disc in fritted funnel 718 is forward flushed so that it is filled with fresh synthetic urine. To the extent possible, air bubbles are removed from the bottom surface of the fritted disc and the system that connects the funnel to the reservoir. The following procedures are carried out by sequential operation of the 3-way stopcocks:

1. Excess fluid on the upper surface of the fritted disc is removed (e.g. poured) from fritted funnel 718.
  2. The solution height/weight of reservoir 712 is adjusted to the proper level/value.
  3. Fritted funnel 718 is positioned at the correct height relative to reservoir 712.
  4. Fritted funnel 718 is then covered with fritted funnel cover 722.
  5. The reservoir 712 and fritted funnel 718 are equilibrated with valves 728 and 740 of stopcock assemblies 726 and 738 in the open connecting position.
  6. Valves 728 and 740 are then closed.
  7. Valve 740 is then turned so that the funnel is open to the drain tube 744.
  8. The system is allowed to equilibrate in this position for 5 minutes.
  9. Valve 740 is then returned to its closed position.
- Steps Nos. 7–9 temporarily "dry" the surface of fritted funnel 718 by exposing it to a small hydrostatic suction of ~5 cm. This suction is applied if the open end of tube